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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/774,939	02/09/2004	Haim Emil Dahan	09420.0001-00000	8623
2882 7590 08342010 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001 4413			EXAMINER	
			SCHELL, LAURA C	
			ART UNIT	PAPER NUMBER
	,		3767	
			MAIL DATE	DELIVERY MODE
			08/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/774.939 DAHAN ET AL. Office Action Summary Examiner Art Unit LAURA C. SCHELL 3767 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 12 August 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-30 is/are pending in the application. 4a) Of the above claim(s) 4.5.8.12-15.19.20.23 and 27-30 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-3,6,7,9-11,16-18,21,22 and 24-26 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

#### Allowable Subject Matter

The indicated allowability of claims 1-3, 6, 7, 9-11, 16-18, 21, 22, 24-26 are withdrawn upon reconsideration and reinterpretation of the claims and the references. Rejections based upon the reconsideration and reinterpretation of the claims and references follow.

### Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 1, line 14 and claim 16, line 10 both recite the phrase "fluid drawn into and retained in the indicator pathway". While the examiner has found antecedent basis for the fluid being drawn into the indicator pathway, the examiner has not found antecedent support for the fluid being "retained in the indicator pathway". Appropriate correction of the specification is requested.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1 and 16, and consequently all dependent claims, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1, line 6 and claim 16, line 5 recite the phrase "at least one indicator pathway having a different volume from the feeding pathway". The examiner has reviewed Applicant's specification and while she has been able to find support for the indicator pathway having a smaller cross-sectional area or longer length than the feeding pathway, or a combination of both, there is no explicit support in the specification for the indicator pathway having a different volume than the feeding pathway. Also, even if the cross-sectional area and length are different from the feeding pathway, it is still possible that a combination exists in which it is the same volume as the feeding pathway. Therefore "having a different volume from the indicator pathway" is being considered new matter.

#### Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1, line 5 claims a second opening "in communication with the baby's mouth". Claim 1, lines 9-10 claim a second opening "in

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direct fluid communication with the baby's mouth". Claim 16, line 4 claims a second opening "in communication with the baby's mouth". Claim 16, line8 claims a second opening "in direct fluid communication with the baby's mouth". As the claims are currently worded, the baby's mouth (a part of the body) is being claimed. Changing the phrasing such that the claim language recites "a second opening adapted to be in communication with the baby's mouth" would overcome the 101 rejection.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Smaczny (US Patent No. 3,260,462). Smaczny discloses an apparatus, comprising: at least one feeding pathway for fluid flow from a fluid source to a baby's mouth (Fig. 3 for example, the feeding pathway could be interpreted as c3), wherein the feeding pathway has a first opening in communication with the fluid source (the bottom end of c3 would be in communication with the fluid source) and a second opening in communication with the baby's mouth (end connecting to A is in communication with the baby's mouth via the fluid's path through a); and at least one indicator pathway (b3 and a is being interpreted as the indicator pathway) having a different volume from the feeding pathway (because b3 is longer in length than c3 it has a different volume than feeding

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pathway c3) for indicating the amount of fluid provided to the baby's mouth through the feeding pathway (b3 is perfectly capable of performing this function), wherein the indicator pathway has a first opening in communication with the fluid source (bottom opening of b3) and a second opening in direct fluid communication with the baby's mouth (top opening of a is the opening that would be in direct communication with the baby's mouth), whereby the amount of fluid drawn into and retained in the indicator pathway is indicative of the amount of fluid drawn into and retained the feeding pathway (since pathway b3/a is longer than pathway c3, the fluid drawn into the indicator pathway would take longer to travel through and therefore can be considered to be retained in the pathway as compared to the fluid in feeding pathway c3 which is much shorter. Furthermore the fluid flowing through b3/a can be considered to indicate the amount of fluid flowing through c3 as the definition of "indicative" in the Cambridge online dictionary is: "being or relating to a sign that something exists, is true, or is likely to happen" {http://dictionary.cambridge.org/dictionary/british/indicative}. The word "indicative" has a very broad definition and does not specifically claim or relate how the amount of fluid in the indicator pathway is equal to the amount of fluid flowing through the feeding pathway (for example, it does not specify that the amount of fluid is calculated by means of pressures, lengths, diameter, etc.). Therefore it is the examiner's position that fluid in the indicator pathway b3/a is indicative of the amount of fluid drawn into the feeding pathway, when given its broadest reasonable interpretation). Art Unit: 3767

In reference to claim 18, Smaczny discloses that the indicator pathway and the feeding pathway each have a length and wherein the length of the indicator pathway is substantially longer than the length of the feeding pathway (Fig. 3).

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smaczny (US Patent No. 3,260,462). Smaczny discloses the device substantially as claimed except for the cross-sectional area of the indicator pathway being substantially smaller than the feeding pathway. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the cross-sectional area of the

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indicator pathway to make it smaller than the feeding pathway as a change in size is generally recognized as being within the level or ordinary skill in the art.

Claims 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smaczny in view of Pechenik et al. (US Patent No. 6,588,613). Smaczny discloses the device substantially as claimed except for the feeding and indicator pathways being integral with a nipple and the fluid source being a bottle. Pechenik, however, discloses a baby nipple with a variety of different fluid pathway arrangements (Figs. 2-26 for example) arranged in a nipple, and the fluid source being a connected bottle (col. 5, lines 23-25). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the fluid path arrangements taught by Smaczny and applied them to a baby nipple, as taught by Pechenik, as Pechenik discloses that it is well known in the art to have baby nipples with various flow path arrangements, and applying the flow path arrangement of Smaczny to the nipple of Pechenik would have been an obvious modification.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smaczny (US Patent No. 3,260,462) in view of Wilk (US Patent No. 5,222,940). Smaczny discloses the device substantially as claimed except for gradations along the second pathway. Wilk, however, discloses a similar device (Figs. 1 and 2) which includes gradations along a second pathway (gradations 18 along the pathway leading to mouth portion 26). Therefore it would have been obvious to one of ordinary skill in the

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art at the time of the invention to have modified Smaczny's device by providing gradations along the second pathway, as taught by Wilk, as this would allow the user or an observer to keep track and measure how much fluid is being consumed by the user.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smaczny in view of Rosenfeld (US Patent No. 5,827,191). Smaczny discloses the device substantially as claimed except for the fluid being breast milk and the pathways being adapted to receive breast milk from a mother's breast. Rosenfeld, however, discloses a similar fluid path/feeding device (Figs. 2-5) in which multiple fluid pathways receive breast milk from a mother's breast and are adapted to deliver that milk to the baby's mouth. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Smaczny's device by using the fluid pathway arrangement taught by Smaczny in the feeding device of Rosenfeld, as Rosenfeld teaches that it is known in the art to have breast shields/nipples with multiple fluid/feeding pathways used to deliver breast milk to a baby.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smaczny in view of Buckley et al. (US Patent No. 6,109,100). Smaczny discloses the device substantially as claimed except for the indicator pathway including a check-valve to prevent backflow of fluid. Buckley, however, discloses a similar fluid delivery device (Figs. 1-5) in which the fluid source is a bottle (21 for example) and the fluid indicator pathway includes a check-valve (Fig. 3, 35 for example). Therefore it would have been

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obvious to one of ordinary skill in the art at the time of the invention to have modified Smaczny's device by placing the flow meter in the nipple of a bottle and by including a check-valve, as taught by Buckley, in order to diversify the device and allow the same fluid-metering/tracking concept to be used by mother's who bottle-feed their baby's as well as to prevent fluid from flowing backwards and comprising the accuracy of the measurement of fluid flow.

#### Response to Arguments

Upon reviewing the application, it was noted that several problems exist with the claims as currently written, thus leading to the 112 and 101 rejections above. It was further noted that the word "indicative" was not being its broadest reasonable interpretation, thus the application of the Smaczny reference above. If the 112 and 101 problems are corrected in independent claim 1, it would be allowable. Also, if independent claim 16 were amended exactly as appears below, independent claim 16 would also be allowable.

Claim 16 (Currently Amended): An apparatus <u>nipple</u>, comprising: at least one feeding pathway for fluid flow from a <u>fluid-source milk cavity area</u> to a baby's mouth, wherein the feeding pathway has a first opening in communication with the <u>fluid-source milk cavity area</u> and a second opening <u>adapted to be in direct</u> communication with the baby's mouth; and

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[[an]] at least one indicator pathway having a different volume length from the feeding pathway for indicating the amount of fluid provided to the baby's mouth through the feeding pathway, wherein the indicator pathway has a first opening spaced apart from said at least one feeding pathway and in communication with the fluid source milk cavity area and a second opening adapted to be in direct fluid communication with the baby's mouth,

whereby the amount of fluid drawn into and retained in the indicator pathway is indicative of the amount of fluid drawn into the feeding pathway.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/ Examiner, Art Unit 3767 /KEVIN C. SIRMONS/ Supervisory Patent Examiner, Art Unit 3767